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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

MARY MADISON, Plaintiff V. Creative Werks, LLC a Delaware Limited Liability Company Defendant.	)	No. 23CV16476 Honorable Judge Manish S. Shah

DECLARATION OF MARY MADISON

Mary Madison, for her declaration, pursuant to 28 U.S.C. §1746, states as follows:

I am over twenty-one years of age and am competent to testify to the matters set forth in this Declaration. The facts stated herein are within my personal knowledge and are true and correct. I was offered a job as the Quality Regulatory Manager at Creative Werks Elk Grove facility on September 20, 2022. My compensation was 95,000.00 dollars per year, plus 10% bonus and a sign on bonus of $2,500.00. See Exhibit 1

The job description referenced in Creative Werks rebuttal to my complaint is for a Regulatory Specialist and therefore is not applicable to me. See Respondent's Exhibit1

I began working on September 27, 2022 at Creative Werks as the Quality Regulatory Manager.

The responsibilities entailed compliance with the Food Safety Modernization Act "hereinafter referred to as FSMA[1]" and other regulatory schemes such as the Bioterrorism Act of 2002 (Food Defense) in addition to being a liaison between customers and the company regarding compliance quality, regulatory and customer requirements (See Exhibit 2 FDA report pg. 8)

[1] FSMA amended the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

On September 27, 2022, I was instructed to report to Creative Werks' Bartlett facility on September 28, 2022 because the FDA was coming to the facility.

DAY ONE OF THE FDA VISIT CONSUMER COMPLAINT REVIEW

After reporting to the facility on September 28, 2022 and while waiting for the FDA inspector Erich Zicher began making disparaging and belittling remarks about the FDA inspector; including but not limited to her effectiveness and abilities as an FDA inspector. Mr. Zicher's remarks along the lines of "she is stupid, she does not know anything etc. He further demeaned her for referencing inadequacies that made it seem that he was incompetent or stupid in the report that she had previously written in July of 2022 relative to the Elk Grove facility. He spent a significant amount of time complaining about her and disparaging her.

Mr. Zicher also spoke at length about his past history as a golf pro and being a music major.

Upon the inspector's arrival at approximately 2:12 pm, she stated that she was there in reference to a customer complaint. She remarked that she was able to gain access into the facility without being properly vetted (See Exhibit 2 pg. 16 § Food Defense) Moreover, the inspector stated that the facility had not been inspected previously because it was not properly registered with the FDA.

The attendees on behalf of Creative Werks were Mr. Erich Zicher, Ms. Angela Knabe, Anupam Sharma and myself. We introduced ourselves to the inspector. Mr. Zicher identified himself as the person most in charge. Subsequently, the inspector issued a notice of inspection--FDA form 482 to Mr. Zicher. We were instructed by the FDA inspector to provide any evidence of being a Preventive Control Qualified Individual, ("hereinafter PCQI"). Mr. Zicher, Ms. Knabe and I provided that information to the inspector.

The inspector began to conduct her interview indicating that there was a consumer complaint made in October of 2021 regarding a Cheetos product that she wanted to discuss (See Exhibit 3). In response, Mr. Zicher refused to produce documents relative to the complaint without permission from the client (See Exhibit 2 pg. 15 § Refusal). He further indicated that he was not aware of a complaint in October of 2021, but was aware of a complaint in May in 2021 regarding a Pepsi Cheeto product (See Exhibit 4 pg. 4). Mr. Zicher indicated that they were aware of a non-conformity relative to burnt seals. He also indicated that they had conducted an investigation, but further indicated that this was no longer an issue, as Creative Werks was no longer doing business with Pepsi (See Exhibit 2 pg. 4 ¶5). There was a somewhat heated discussion between Mr. Zicher and the inspector regarding the timing and length of the investigation.

During the relevant time, Mr. Zicher did not offer any tangible evidence or any particulars on the investigation or any subsequent remedial measures taken to mitigate the non-conformance and to prohibit adulterated food from entering the stream of commerce.

The inspector left at approximately 4:30 pm and indicated that she would return on the next day, Thursday, September 29, 2022.

Mr. Zicher continued to disparage the FDA inspector's competency. He also stated that the production and tendering of documents is not permitted and if we have to produce documents, we are only to show them electronically.

DAY TWO OF THE FDA VISIT SITE INSPECTION

The FDA inspector returned on Thursday, September 29, 2022 at approximately 1:00 pm. The inspector reviewed the consumer complaint from the previous day continuing to make inquiries about the timing and resolution of the complaint. Mr. Zicher again denied having any knowledge of the October 2021 complaint.

The inspector moved on and began doing an audit inspection of the company's records and relevant practices. Mr. Zicher was not initially compliant with the request; refusing to produce the requested information, but ultimately acquiesced. (Def. Ex. 2 Dkt. #81)

The inspector asked about training. Various types of training were identified, including 5S training. The inspector asked what that was and no one could speak to what that was including Mr. Zicher.

The inspector indicated that she wanted to tour the facility. Of course, I wanted to accompany them because I was new and I wanted to see the facility. Mr. Zicher stated that if I was accompanying them on the facility tour my jewelry needed to be removed. He indicated to me that I had a dress on. However, Ms. Knabe stated that I was all right to go, indicating that the company policy stated that one's extremities were to be covered. There was no exposed flesh; my arms and legs were fully covered.

To minimize the discussion, I informed him that I had pants in the car and that I would change.

I was unable to remove one of my screwed-in stud earrings. Per the FDA, jewelry is permissible if it is secured. Further the rule is geared towards those that come in direct contact with food, food-contact surfaces, and food-packaging materials (See 21 CFR Subpart B § 117.10 (b)(4)). By Mr. Zicher's own admission in his declaration, I could not get the earring out. Moreover, he neglected to state that head covers were used that also covered the ears that could have caught

and restrained any particulate from being introduced in the manufacturing facility; therefore, controlling and minimizing any risk.

I did not pose any safety risk, as I was not going to be working on a line or coming into direct contact with any product, surface or packaging material. Thus, it would have been highly unlikely or improbable that any contamination would have occurred.

I contend that any embellishments from my prescription eyeglasses would not have posed a risk for the same reasons.[2] Additionally, the use of goggles could restrain any particulate from being introduced into the manufacturing facility.

I do not paint my fingernails. Mr. Zicher's statement that my nails were painted is patently false.

Further, I contend that my presence during the inspection was not essential, as I had just started and had not been to the facility before. I had no knowledge about the facility and its operation. Additionally, the person that I was replacing, Ms. Knabe did not accompany them either nor was she invited or required to go on the tour.

Ms. Knabe and I remained in the conference room further suggesting that it was not as crucial as Mr. Zicher is now attempting to make the issue to be.

Upon their return from the tour, it was revealed that the FDA inspector had observed improper sanitation being performed.

Another issue arose when the inspector wanted to take sample labels off the line that was running. Initially Mr. Zicher refused and told the inspector that those labels did not belong to Creative Werks, but their customer, Hersey. Mr. Zicher also indicated that they needed permission from the customer to do so.

Ms. Knabe reached out to Teddy Cadet, the Senior QRC Specialist, from Hersey asking for permission to provide the FDA the labels. Mr. Cadet indicated that it was ok to give them the labels, as they were entitled to these materials during an inspection (See Exhibit 5).

There were five (5) observational findings identified by the FDA inspector at the closing meeting on September 29, 2022. These findings ranged from improper record keeping to sanitation and pest control issues.

[2] Further, even knowing that an inspection was going to take place, there is nothing that could have been done to replace my eyeglasses on such short notice.

The other attendees were perplexed that the inspector raised an issue about the records not being properly kept. Specifically, the records were not dated. No one seemed to know or understand the relevance or importance of the issue raised.

Subsequently, that evening, Mr. Cadet followed up asking what was the reason for the FDA visit.

In response, Mr. Zicher sent out an email entitled "FDA Inspection Routine Inspection" at 9:38 pm on Thursday, September 29, 2022. In it, Mr. Zicher discussed the Pepsi consumer complaint along with identifying the five (5) observations made by the FDA Inspector (See Exhibit 4).

In sum, on September 28 and 29, 2022, I engaged in protected activity[3] when I participated in a FDA audit/inspection that resulted from a consumer complaint at Creative Werks Bartlett facility.

FOLLOW UP AFTER AND DEBRIEF OF THE FDA VISIT

On Friday, September 30, 2022, Mr. Zicher solicited input from myself, Ms. Knabe and others on how to couch the FDA visit to craft his response and inform other clients of the FDA visit.

On September 30, 2022, I began performing a Root Cause Analysis of the deficiencies identified in the closing meeting with the FDA.

In performing the Root Cause Analysis of the findings, I observed that there were a number of issues of non-compliance with FSMA and the Bioterrorism Act of 2002.

I engaged in protected activity when I spoke with Mr. Steve Schroeder on Friday, September 30, 2022 regarding the FDA inspection while at the espresso machine. He asked me about the inspection and in particular about what happened with the Pepsi complaint. I indicated that it was an issue relative to the timing of the complaints and investigation. I also indicated that the requests from the FDA inspector were not unreasonable and that documents were not produced to the FDA as requested. Mr. Schroeder stated that he "wanted to change the culture to be more transparent." He also stated that "he hoped that I could be of help to the company."

I further indicated that I was in the process of drafting correspondence to help clarify the requests and findings of the FDA inspector during the visit. Mr. Schroeder told me that he had sent some questions to Mr. Zicher regarding the FDA visit and he asked me to ask Mr. Zicher to share the questions that he sent him with me so that I could respond to them.

As promised, later that afternoon, on Friday, September 30, 2022, I presented for review the corresponding rules, regulations and statutes that underscored the requests and observations

[3] As defined by 21 U.S.C. § 399d (a)(1)

made by the FDA inspector to identify and shore up any outstanding gaps for compliance (See Exhibit 4 pg. 1).

During the relevant time, I had no idea that a number of documents requested did not exist. Nor did I understand that documents that did exist did not meet the requirements of 21 CFR 117 and the food defense under the Bioterrorism Act of 2002.

REMEDIATION OF OUTSTANDING NESTLÉ AUDIT DEFICIENCIES

In attempting to remediate outstanding customer audit findings from July of 2022, I discovered that the food safety plans were either inadequate or did not exist in contravention of 21 CFR 117 and other food defense requirements under the Bioterrorism Act of 2002. Additionally, I also discovered that Creative Works had repeated non-conforming audit findings that still had not been mitigated or remediated.

For example, it is a documented fact that Creative Werks only had four (4) food safety plans. Plans that were based on Hazard Analysis Critical Control Points, "hereinafter HACCP[4]." This is contravention of 21 CFR 117.126. Further, none of the required plans were developed for Nestlé.

HACCP is the internationally recognized standard that was the forerunner and the precursor to Hazard Analysis and Preventive Control, "hereinafter HARPC." HARPC became the standard in the United States when the Preventive Control for Human Food, "hereinafter PCHF" rule became final in September 2015. PCHF rule requires food facilities to have a food safety plan in place that includes an analysis of hazards and risk-based preventive controls to minimize or prevent the identified hazards. (FDA https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food)

HARPC-The Preventive control systems emphasize prevention of hazards before they occur rather than their detection after they occur. [5]

Creative Werks is a registered facility under the Bioterrorism Act of 2002, which subjects Creative Werks to the FDA's PCHF rule.

In reviewing Creative Werks records during that relevant period there was no evidence that Creative Werks had ever had PCHF compliance using the HARPC standard.

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[4] The FDA defines HACCP as a "management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product" (FDA 02/25/2022).

[5] Sherod, Anne (11 May 2015). "The ABCs Of Building A Food Safety Plan: From HACCP To HARPC". *foodonline.com*. Archived from the original on 14 December 2018. Retrieved 2 August 2023.

The FDA clearly states that: “This hazard analysis must be written, regardless of whether any hazards requiring a preventive control are identified.” (FDA-Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry § 1.2 2).

The FDA Guidance documents represent the “FDA's current thinking on a topic or FDA’s interpretation of our policy on a regulatory issue” (FDA 2023).

Further, a plan is required even if it is the same product being run at a different facility See 21 CFR 117; Also, see FDA Frequently asked questions on PCHF. https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma

I communicated to Mr. Zicher these deficiencies and our non-compliance that underscored the audit deficiencies. I was told by Mr. Zicher on several occasions that Donna Bjurlin, from Nestlé, was being picky and that he was not inclined to make any changes (See Exhibit 6). I was also instructed by Mr. Zicher not to reference the regulations and standards when corresponding with Donna on behalf of Nestlé.

MEDFAST POTENTIAL NEW CUSTOMER-BENSENVILLE

On October 3, 2022, I met Mr. Zicher at yet another Creative Werks facility in Bensenville to meet with a potential new customer Medfast.

While we were waiting for the potential clients, Mr. Zicher and I discussed the FDA audit/inspection. We discussed the complaint. We also discussed how it seemed that Creative Werks was unaware that it had non-conforming/adulterated product that it should have been aware of since May of 2021 and did nothing to prevent it from entering into the stream of commerce for human consumption. I shared with him that a good starting point was to understand what standards we needed to comply with based upon our operations. I also shared with Mr. Zicher that Mr. Schroeder wanted him to share with me the questions that Mr. Schroeder had sent to him regarding the FDA visit on September 28-29, 2022.

Mr. Zicher indicated that I did not understand the culture there and that he would not be providing me with the information Mr. Schroeder asked me to ask him to share with me. He also indicated that he and Ron Sammeth, the COO, decided what Mr. Schroeder should see and know.

Later during the Medfast visit, several questions were raised by them relative to basic requisites under FSMA relative to likelihood/severity of occurrences for hazards related to their product. For example, the issue arose as to whether Creative Werks performed environmental monitoring. The question was posed after Medfast representatives saw the storage of large amounts of

corrugated boxes in the warehouse. The warehouse presented conditions that supported optimal growth for mold and other microbes. This is a reasonable and foreseeable hazard that could have been easily identified and managed from the proper execution of a science risk based hazard analysis.

BLUE DIAMOND GROWERS AUDIT-BENSENVILLE

On the next day, October 4, 2022, I began preparing for an upcoming audit that I was tasked to facilitate on October 6, 2022 on behalf of Blue Diamond Growers "hereinafter BDG." BDG had sent over an audit plan of specific items that they wanted to review during the audit (See Exhibit 7).

In my preparation for the BDG audit, I found a number of deficiencies and in an attempt to remediate them prior to the audit, I informed Mr. Zicher of these deficiencies (See Exhibit 8).

I was told by Mr. Zicher not to worry about the deficiencies because in his experience "no one reads the documents" and to "use whatever documents we have."

I was instructed by Eric Zicher, Director of Food Safety to provide false, inaccurate and misleading information to clients after I specifically pointed out deficiencies in the documentation.

On October 6, 2022, the auditor, Keira Kaur Dhillon came to perform the audit. We began our introductions; Ms. Dhillon went first indicating that one of her previous employers was Kraft Foods. I went next and Mr. Zicher went last. Mr. Zicher told Ms. Dhillon that they had something in common because they both had worked at Kraft. She in turn asked him who was the CEO when he worked at Kraft? Mr. Zicher did not and could not answer her question--The room was filled with silence.

Seemingly to deflect the awkward situation, Mr. Zicher made remarks poking fun at me to Ms. Dhillon that I had all these tabs open on my computer relative to the documents that they had requested to review.

I responded to the effect that since they were kind enough to send over a comprehensive list of what they wanted to review during the audit and in the interest of everyone's time, it seemed prudent to be prepared and not to have to search for documents (See Exhibit 7).

The auditor remarked that the audit exhibited readiness because of the readily available documents (See Exhibit 9).

Unfortunately, there was an issue identified by the auditor in one of the documents she reviewed that could have been identified and remediated. This was not the case because I was instructed to ignore the deficiencies identified (See Exhibit 8).

FOLLOWING UP ON UNREMEDIATED OUTSTANDING NESTLÉ AUDIT ISSUES

In an effort to follow up on the outstanding audit non-compliances relative to Nestlé that had been due and owing since July of 2022, I again broached the outstanding issues from the audit along with conversations[6] that I had with Donna Bjurlin from Nestlé Corporate Quality with Mr. Zicher. Mr. Zicher stated that "her expectations were not realistic and that she was being picky."

After closer examination of the nonconformities, Creative Werks documentation, Nestlé requirements and the regulations, I discovered that her requests were directly tied to documents, procedures and analyses that would have resulted from a proper Food Safety Plan and other scientific risk based requisite and prerequisite programs, such as science risk based hazard analysis, Good Manufacturing Practices, ("hereinafter GMPs"), allergen controls, supply chain management, and Integrated Pest Management among other programs.[7]

For example, the Nestlé audit noted that Creative Werks failed to properly vet or produce evidence of proper receiving of products, even though it may have come from them initially (See Nestlé audit Exhibit 10).

To demonstrate that this was a common practice of not exercising proper food safety/defense, Mr. Zicher instructed me to not follow various requirements because the product was coming from Mondelez (See Exhibit 11).

Supplier verification is a requisite relative to food safety/defense. Further, Creative Werks purchased commodities from its clients that it packaged for sale and had a duty to ensure that food was safe and not adulterated before allowing it to be introduced into the stream of commerce for human consumption. Further, a Foreign Supplier Verification Program, ("hereinafter FSVP"), would be required when purchasing commodities outside of the United States for resale in the United States (See 21 CFR Subpart G).

There was no adequate mechanism in place nor did Creative Werks consistently follow whatever procedures it had in place relative to supplier verification (See Exhibit 12). Additionally, I had

[6] A longstanding biweekly meeting was held by Nestlé to address the outstanding audit deficiencies.
[7] The lack of a proper pest management program was evidenced by one (1) of the observations made by the FDA inspector on September 29, 2022 that noted there were pest control issues at both the Elk Grove and Bartlett facilities (See Exhibit 2 pg. 16 cross reference FDA July 2022 EIR 3010131930). The same observations were noted for sanitation and record keeping.

been instructed to release material that was being held for non-conformance based on this same premise on several other occasions.

TRACEGAINS DOCUMENT REQUESTS

I began reviewing TraceGains[8] requests for documents and searching for the requested documents from numerous clients. It was during this process that I began to fully understand that there were no specific documents relative to each client and their respective products. For example, one client was looking for a recall plan among other things. The only recall plan was for General Mills. The client was not General Mills (See Exhibit 13).

There were TraceGains requests dating back to 2021. These requests were not able to be fulfilled because of the lack of proper food safety plans, as well as compliance with customer requirements, prerequisite and requisite programs among other metrics. These requests mirror the audit deficiencies identified in the Nestlé audit.

Mr. Zicher makes a patently false and misleading statement in his declaration that the TraceGains requests at issue of almost 150 requests were a result of ongoing requests from a previous customer that no longer did business with Creative Werks (See Exhibit 14 pg.1).

The requests were made from various clients that were actively doing business with Creative Werks. Another example is Wilton Brands. Wilton Brands began requesting documents in 2021 and in October of 2022 began actively seeking these documents demanding to know why these documents were not being provided (See Exhibit 14 pg. 2)

The common practice had been recycling documents between customers to meet whatever requests, leading customers to believe that the documents provided to them by Creative Werks were inherent to their particular operation; when in fact they were not.

Customers relied on the information provided by Creative Werks for their business records and to demonstrate compliance with the FFDCA (FSMA) and relevant regulations as applied to food safety. For example, Nestlé was confronted with a compliance audit and had unmet past due deadlines of several months for outstanding audit deficiencies. I was contacted by Nestlé to provide updates and reasonable remediation steps. I reached out to Mr. Zicher and when he finally responded, he ignored issues that were a direct outgrowth or part of the mandated Food Safety Plans and other matrices or with non-relevant and noncompliant responses (See Exhibit 6).

[8] TraceGains is an online exchange platform for requesting, sending and receiving documents across the supply chain.

Further, I emailed Mr. Zicher about the voluminous document requests. I also told him I was uncomfortable with providing any false and misleading information to the customer based upon him previously instructing me to do so. TraceGains sent out a weekly status alert relative to documentation requests. Mr. Zicher was fully aware of the situation. Mr. Zicher once again has made patently false and misleading statements (See Exhibit 14).

FOOD SAFETY PLANS

I repeatedly asked Mr. Zicher about the Food Safety Plans and how they were constructed and what scientific basis was used. Finally, Mr. Zicher indicated that he used the Food Safety Preventive Control Alliance public draft edition participant manual that he received during training while working at Kraft as the basis for drafting the plan in addition to excerpts from the FDA template (See Exhibit 15).

None of these referenced documents supported how he derived the information referenced in his plan. There were also fundamental deficiencies with the document such as it being updated[9]. Even using the incorrect standard of HACCP, the application of the HACCP principles were still incorrect, as the severity/likelihood matrix did not support the information contained on the HACCP plan.

Mr. Zicher could not tell me the science, the method or point to any analysis to justify what was contained in the food safety plan he drafted relative to Dunkaroos that was to be the template for any other food safety plan (See Exhibit 15).

I explained to Mr. Zicher that such a plan was a cross-functional[10] document supported by process owners and other contributors founded on scientific principles such as Standard Operating Procedures[11] based upon scientific and standardized test methods and other fundamental principles, etc.

Creative Werks also lacked change control management, an essential function ensuring that various requirements are being met to remain compliant with FSMA and other relevant statutes. Further, change management is directly correlated to preventive controls such as validation, verification and reanalysis relative to 21 CFR 117 §§ 160, 165 & 170. This deficiency was also noted in the Nestlé audit (See Exhibit 10 CAR # 23)

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[9] Undated documents are in contravention of the record keeping requirements of 21 CFR 117.301.

[10] Cross-functional is defined as denoting or relating to a system whereby people from different areas of an organization work together as a team. Cambridge Dictionary https://dictionary.cambridge.org/us/dictionary/english/cross-functional.

[11] Creative Works did not have Standard Operating Procedures ("hereinafter SOP's). Work instructions were used instead. A number of these were stale dated.

POSITIVE SALMONELLA

During the week of October 24, 2022, it was discovered that there was positive testing for Salmonella at the Elk Grove facility. Prerequisite and requisite programs needed to manage such microbial hazards or any other hazards were not in place to reduce or mitigate the spread of these causative agents of food borne diseases. Nor did Creative Werks during the relevant time have any Standard Operating Procedures relative to microbial hazard management or any other biological, chemical, physical or radiological hazard.

Creative Werks handles Ready To Eat foods, ("hereinafter RTE") that lack any further processing or kill step to eliminate or reduce hazards. Therefore, it is incumbent that a science risk based analysis be implemented to manage identifiable and foreseeable risks to prevent food from being adulterated and introduced into the stream of commerce for human consumption (21 CFR 117).

It can easily be inferred that the consumer complaint filed in October of 2022 was a direct result of the lack of proper food safety and hazard analysis (risk management) at Creative Werks. The complaint was tied to cereal; a RTE (See Exhibit 16). More specifically, it can be reasonably inferred that the root cause of the reported October 2022 illness was due to Creative Werks willful failure to adhere to the mandate of food safety laws and regulations relative to ensuring that food is not adulterated when it enters into the stream of commerce (21 CFR 342).

CREATIVE WERKS PURPORTED TO HAVE A SEE SOMETHING SAY SOMETHING POLICY.

I drafted a very high-level risk analysis on October 20, 2022.

On the morning of October 21, 2022, I emailed Ms. Gretchen LeMay, VP of People and asked to speak with her on Friday October 21, 2022. We agreed to meet on that following Monday (See Exhibit 17). My intent was to speak with her about the outstanding issues described above.

On Friday afternoon, I spoke with Mr. Schroeder, the owner of the company regarding outstanding compliance issues and presented him with the risk analysis dated October 20, 2022 (See attached Exhibit 18).

During our conversation, Mr. Schroeder remarked that he did not understand what I was saying to be true because Erich told him that he worked at Kraft. I told him I could not speak to Mr. Zicher's actions, but that I was sure of what I was saying. I also told him that I had been formally trained and had years of experience with this kind of work. Mr. Schroeder also told me that I should have been trying to make nice with my boss since I had been there less than thirty (30) days.

It was my understanding that Mr. Schroeder would read the report and revert back to me for further discussion

Monday October 24, 2022 came and went and no one spoke with me nor did I have a meeting with Ms. LeMay.

On October 26, 2022, as I was leaving to go home, I was stopped, by Wendy from HR, and instructed to go into the conference room. It was at that time that Gretchen LeMay, VP of People, told me and presented me with a letter that I was being suspended for the conversation that I had with Mr. Schroeder (See Exhibit 19).

I was further told and it was memorialized in the same letter that an outside attorney would be conducting an investigation into the matters and allegations raised to Mr. Schroeder.

When I pressed Ms. LeMay on what grounds that I was being suspended on, she stated that my allegations were unfounded.

I offered her support of my position. I was instructed by her to save it for the attorney.

At no time after the conversation with Mr. Schroeder did he or anyone else follow up with me regarding the report. Nor was I involved in any type of investigation prior to being informed of my suspension.

I believe that my suspension on October 26, 2022 was in retaliation for my having presented the risk analysis to Mr. Schroeder. I also believe that I engaged in protected activity when I provided the risk analysis that detailed violations of the Food Safety Modernization and Bioterrorism Acts.

In further retaliation, I was not paid my sign on bonus on October 27, 2022 as referenced in my offer letter (See Exhibit 1).

After I requested to have an attorney present at the meeting with Creative Werks outside legal counsel, I was further retaliated against when my suspension transitioned from with pay to without pay (See Exhibit 20). Additionally, I was told by Ms. LeMay that I did not need an attorney because this was an in-house matter and the counsel would be acting in the capacity of an independent fact finder.

I communicated to Creative Werks the adverse employment actions, which were taken against me, including but not limited to being retaliated against for identifying and raising

non-compliance issues to Mr. Schroeder related to violations of FSMA. I further addressed the issue of not being afforded an opportunity to be a part of any investigation (Exhibit 21).

I requested my personnel file and it was provided on November 8, 2022 by Gretchen LeMay, VP of HR (See Exhibit 20). There was nothing in the file adverse except the suspension letter. I further reject the contention that I was not meeting Respondent's expectations and that they would have taken the same actions toward me. This is in direct contradiction to the fact that I was issued a written letter of suspension outlining the fact that my suspension was due to the conversation I had with Mr. Schroeder on Friday October 21, 2022 regarding the report dated October 20, 202 (See Exhibit 19). Further, according to Ms. LeMay there was nothing in the personnel file except the suspension letter and onboarding documents (See Exhibit 20).

Further, to date Creative Werks has not and cannot point to any non-retaliatory reason for suspending me. Nor can Creative Werks point to any company or public policy that I violated relative to my employment to warrant my suspension and de facto discharge/termination.

Further, Mr. Zicher publicly acknowledged in an email dated September 29, 2022, to management and the salaried associates of Creative Werks, that I had made positive contributions to the FDA audit (See Exhibit 4). Further, there was positive feedback from the Blue Diamond Growers audit indicating that it was an outstanding well-organized audit (See Exhibit 9). Further, Mr. Zicher also credited me for resolving a longstanding unresolved issue with Nestle (See Exhibit 10).

In regards to the non-conformances noted in the Blue Diamond Growers Audit, were issues that I had raised with Mr. Zicher on October prior to the audit and he indicated

I attended a meeting with the outside counsel on December 20, 2022, due to the meeting having to be rescheduled because of Defendants attorney becoming ill. Attorney Kim Ross of the Law Firm of Ford Harrison indicated that she was an independent fact finder. Attorney Ross is an employment lawyer, who did not demonstrate that she had an understanding of the subject matter contained in the risk analysis. We spoke for over 6 hours. Only an hour was spent talking about random excerpts of the report.

During the time we spoke, we talked about my background, past work experience and unrelated things to the issue at hand including the alleged after acquired evidence. It was also communicated to her that this investigation was contrived, a farce and a subsequent remedial measure to pretext.

In January of 2023, Creative Werks counsel contacted my legal counsel and made an offer of $50,000 indicating that I could not come back to work at Creative Werks because Eric Zicher could not work with me. He also indicated that my assertions and allegations were unfounded.

I requested my personnel file again to review the findings of the investigation that supported their contentions that my assertions were unfounded. Creative Werks declined to provide me my personnel file in contravention to the Illinois Personnel Review Act or the results of the investigation (See Exhibit 22).

Craig Thorstenson also of Ford Harrison stated that Creative Werks was claiming privilege and would not be sharing the findings based on client-attorney relationship. This explanation for denying me access to their findings contained in my personnel file belies the assertion that the outside counsel from Ford Harrison was acting as an independent fact finder.

Attorney Hoffman raised issue with Defendants claiming privilege. (See Exhibit 22)

Craig Thorstenson indicated that nothing new had been added to the Personnel file. (See Exhibit 22)

Defendants admitted in their answer Dkt. #53 ¶95 that through my legal counsel, Creative Werks was again provided with my various theories of causes of actions, including but not limited to what I contend was retaliation amongst other things. I also contend that Creative Werks conspired to violate my protected rights. Creative Werks acknowledged that Creative Werks was aware of these theories and admonished me to make a counter offer, to their proposed severance offer, as they would not raise their offer until such time (See Exhibit 23).

I made a counter offer and their deadline to reply was April 17, 2023. Communications ceased and I filed my claim with OSHA on April 21, 2023.

Acceptance of Defendants severance offer was contingent upon me waiving any claims that I had against.

RESPONDENT'S POSITION STATEMENT IN RESPONSE TO THE APRIL 21, 2023 WHISTLEBLOWER CLAIM

I reject Creative Werks position on the matter at hand. First and foremost, Creative Werks is unable to support any of its assertions with relevant facts, rules, regulations or statutes to support their contentions, including but not limited to that I was terminated for incompetence.

To date Defendants have not been able to point to errors in the risk analysis that can be supported by fact, law or science.

I also categorically deny and vehemently disagree that I am incompetent.

Creative Werks has tried to convolute and malign the issue with facts that are not relevant and that are taken out of context relative to the fee waiver matter. To be extremely clear, I still contend that on that day and time when I applied I did not have the funding. Further, court records will show that I demonstrated this fact.

I further reject Mr. Zicher's assertion that I was hired to write the food safety plans. Further, the mere assertion that I was hired to write the plans underscores the fact that there were not any such plans. Further, Mr. Zicher does not point to anything to support this contention.

Additionally, the construct of a food safety plan is a cross functional and multidisciplinary function. Consequently, this contention could not be legitimate. Further, Creative Werks lacked the basic infrastructure, like standard operating procedures among other things, which Mr. Zicher alleged to be responsible for[12] to even begin developing such plans.

Hence the declaratory statement from Mr. Zicher is in contradiction to Creative Werks expert witness who claims that Creative Werks was compliant. Further, by Creative Werks own admission they lacked the requisite components of a food safety plan (See Nestlé audit CAR# 1 & 2). These two (2) competing interests and schools of thought create an unexplainable anomaly squarely putting Creative Werks in a conundrum.

I further reject the contentions of Creative Werks' expert witness who claims to be a Food Scientist, but yet in reality by her own admission on her LinkedIn page is only a microbiologist[13]. This claim of being a food scientist is disingenuous and patently false (See Exhibit 24).

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[12] See FDA REPORT 3010131930 dated July 14-15, 2022 pg. 6.

[13] According to the Bureau of Labor and Statistics: Food scientists and technologists use chemistry, biology, and other sciences to study the basic elements of food. They analyze the nutritional content of food, discover new food sources, and research ways to make processed foods safe and healthy. Food technologists generally work in product development, applying findings from food science research to develop new or better ways of selecting, preserving, processing, packaging, and distributing food. Some food scientists use problem-solving techniques from nanotechnology—the science of manipulating matter on an atomic scale—to develop sensors that can detect contaminants in food. Other food scientists enforce government regulations, inspecting food-processing areas to ensure that they are sanitary and meet waste management standards.

Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Agricultural and Food Scientists, at Agricultural and Food Scientists : Occupational Outlook Handbook (visited August 3, 2023).

The Bureau of Labor and Statistics defines a Microbiologist as a person who "studies microorganisms such as bacteria, viruses, algae, fungi, and some types of parasites. They try to understand how these organisms live, grow, and interact with their environments."
Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Microbiologists, at https://www.bls.gov/ooh/life-physical-and-social-science/microbiologists.htm (visited July 26, 2023).

Further, Dr. Knutson only has worked thirty-eight (38) months as a microbiologist in entry level positions in an industrial setting only performing routine tests, despite having a PhD according to her LinkedIn profile. Moreover, this work experience predates the enactment of any food safety law by almost ten (10) years. The concentration of Dr. Knutson's working career over the past two (2) decades seems to be centered around teaching and cannabis[14].

Further, if one is an expert, in any particular field of discipline, it would be par for the course, for the expert to be extremely familiar with governing rules, regulations, laws and best practices governing the subject matter and the rules of evidence to present such information. In addition to being able to apply them accurately and correctly as opposed to ignoring them or being in contravention of the very standards in which they allegedly contend to be proficient.

The FDA provides a rudimentary and basic understanding of the requirements and the statute outlined on the FDA's frequently asked questions webpage that is presented in non-technical and scientific terms that is available to everyone. Frequently Asked Questions on FSMA | FDA Further, by chance it happens to speak directly in detail about some of the issues that are in contention here.

For example, it clearly states that each facility needs a food safety plan and that each item requires a plan. Further, it is telling that Dr. Knutson did not take these and other factors into account in her analysis and that she could arrive at the conclusion she did predicated on the facts in this case.

Further, what is even more telling is that as a PhD recipient, scientist and alleged technical writer that Dr. Knutson either did not know or miserably failed to cite references in support of her theories or conclusions. This is a basic undergraduate scientific principle and even further a basic writing principle learned in grammar school.

Other telling indictments of Dr. Knutson's lack of understanding about food safety, HACCP and the precursor to HARPC and other matrices surround statements that she makes relative to the fact that there are no International Standards. One of the very things that she purports to be certified in is HACCP which takes direction from the Codex Alimentarius[15]an international standard. It is further common knowledge that FDA routinely adopts in full or in part food

[14] Schedule I controlled substance under federal law on par with LSD and heroin that is not federally regulated for human consumption.

[15] The Codex Alimentarius is a collection of internationally adopted food standards and related texts presented in a uniform manner. These food standards and related texts aim at protecting consumers' health and ensuring fair practices in the food trade. The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade. The United States has been a member of the Codex Alimentarius since 1963 (Members | CODEX ALIMENTARIUS FAO-WHO) (International & Interagency Coordination | FDA).

safety standards from the Codex Alimentarius (See Exhibit 25). Therefore, to espouse such patently false information is an indictment of sheer incompetence and unreliability. Dr. Knutson's actions are further reprehensible and unconscionable due to the fact that we live in an age where information is readily accessible and plentiful by just doing a simple Google search.

Further, Dr. Knutson nor Zicher nor Schroeder nor its counsel seem to understand that FSPCA is not the statutory and REGULATORY mandate outlined in the FFDCA as amended by FSMA.

They all further seem to specifically lack the understanding and the requisite knowledge that SQF and other third party audits are voluntary under the FFDCA and do not comport to compliance with FFDCA. (See Exhibit 26)

I further reject the authenticity of the alleged documents that Dr. Knutson reviewed because they were not attached as required for reference. Further, Creative Werks provided an incorrect job description that is not commensurate with the position in which I held.

I contend that Creative Werks conduct of providing an incorrect job description was deliberate, intentional and done in bad faith to support their erroneous contention that I was responsible for writing the Food Safety Plans "hereinafter FSP."

This conduct and practice of providing incorrect information is extremely telling and further supports other allegations of Creative Werks misconduct relative to providing non-relevant documents in an effort to skirt and avoid compliance with FSMA and the Bioterrorism Act of 2002. Additionally, I contend that this is an example of Creative Werks deliberate and willful actions to continue to retaliate against me and substantiate the adverse employment actions taken against me. Additionally, it further underscores Creative Werks pattern and practice of contrivances in this and other instances.

UNSUPPORTED STATEMENTS

Dr. Knutson chose not to support her findings by fact, law, science, peer review or even a blog. Based upon that choice, this expert opinion devolves down into a mere unsupported weak opinion based on inconclusive and conclusory statements.

I further reject Dr. Knutson's contentions that Creative Werks is/was compliant with the prevailing mandates based upon the twenty-six (26) documents reviewed by Dr. Knutson. Further, in sum, Creative Werks had in excess of twenty-six (26) customers who ran multiple food items that were wrapped, naked or blended. Creative Werks' three separate (3) facilities, purchased and resold commodities for human consumption, as well as manufactured contact and non-contact food grade packaging.

Additionally, it was well documented that Creative Werks did not have preventive controls in place, as PCHF rule had not been complied with. A requisite of compliance to an adequate food safety plan and the determinative factor of preventive controls. This was affirmed and evidenced by their own admissions. (See Nestlé audit pg.1) Conclusively, these facts do not demonstrate compliance or support her opinion.

Further, as an alleged consummate expert in food safety, Dr. Knutson should have known immediately that the absence of such documents like hazard analysis, preventive controls, supply chain program, vulnerability assessment etc… does not comport with compliance. Dr. Knutson should have further known as a microbiologist that "RTE" foods that are handled and stored require an analysis to determine any associated hazards and then how to manage the risk (preventive controls). A failure to do so is a dereliction of the duty of care imposed upon Creative Werks to ensure food that is introduced into the stream of commerce is safe for human consumption and not adulterated in accordance with 21 CR 342.

Even if Dr. Knutson did not know anything else this concept would or should have definitely been in her wheelhouse as a degreed PhD Microbiologist. Sadly, this is a fundamental concept that is taught on an undergraduate level. Dr. Knutson's inability to reconcile this principle with her education and her boasting of having taught an approved curriculum over forty (40+) plus times is testament to her sheer incompetence in food safety even from a scientific perspective.

I hired an expert witness, Dr. Katherine Adams Hutt, to rebut Defendants opinion (See Exhibit 27)

Dr. Hutt is a consummate professional and expert in Food Safety Regulations and contributed to the framework of the Food Safety Regulations.

I further reject the contention that I lacked professionalism relative to speaking with the owner.

First and foremost, the company and its owner touted a mantra of a "see something say something[16]" policy that they continuously reiterated in meetings and by post.

Further, the owner on an ongoing and regular basis spoke with his employees daily about a myriad of things. He himself espoused transparency among other things and had personally on several occasions stated that he hoped that I was helping the company along.

It was with great trepidation that I approached Mr. Schroeder even after having contemplated a backlash as a response, as evidenced by my request to speak to Ms. LeMay. However, I could not reconcile in my mind how someone who builds a successful business, purports to care about

[16] The FDA inspector makes note of this policy and references it in her report See Exhibit 2 pg. 16.

their employees, tries to create a decent and palpable work environment, engages in philanthropic efforts and makes himself available and accessible to his employees would want to find themselves blindsided, hoodwinked and bamboozled about their operation. Notwithstanding being flogged with possible criminal charges and economic woes.

Further, as Dr. Knutson noted, I am held to a higher standard and I learned relatively quickly that the standards were not being met. Additionally, being held to a higher standard and being a leader means that you have to be accountable for your actions and inactions. Conversely, if something adverse had occurred without a doubt the scenario would have been "you should have known better and you should have said something."

Additionally, there are a number of instances within the industry that have occurred as a result of people not following the standards. e.g. Blue Bell creameries and Peanut Corporation of America are prime examples of companies not following basic safety rules. In particular, it was noted in a Press Release from the Department of Justice in July of 2020 that the Blue Bell Creameries Listeria case "was particularly concerning because of the disregard of basic food safety rules and the impact those actions can have on the health and safety…" according to Robert E. Craig Jr., Special Agent in Charge of the Defense Criminal Investigative Service Mid-Atlantic Field Office.

The Press Release also went on to say:

"The health of American consumers and the safety of our food are too important to be thwarted by the criminal acts of any individual or company," said Judith A. McMeekin, Pharm.D., Associate Commissioner for Regulatory Affairs, FDA. "Americans expect and deserve the highest standards of food safety and integrity and we will continue to pursue and bring to justice those who put the public health at risk by distributing contaminated foods in the U.S. marketplace."
https://www.justice.gov/opa/pr/blue-bell-creameries-agrees-plead-guilty-and-pay-1935-million-ice-cream-listeria

Another press release from the Department of Justice, relating to a supply chain recipient of the tainted peanut butter from the Peanut Corporation of America, predating the Food Safety and Modernization Act of 2011 underscores the long time initiative and commitment of the FDA to food safety.

"Product safety has to be a high priority for every manufacturer of foods sold in the United States" says Stephen M. Ostroff, Deputy Commissioner for Foods and Veterinary Medicine at the FDA. "FDA is working with food producers to promote compliance with food safety

requirements, but if problems occur and are willfully ignored, we will use all available resources to protect American consumers from unsafe food."

https://www.justice.gov/opa/pr/conagra-subsidiary-sentenced-connection-outbreak-salmonella-poisoning-related-peanut-butter

Further, as a consumer, I am concerned about the health and welfare of myself, my family and society at large, as the products that are handled at Creative Werks are common brand name, brand leading, household foods that people of all ages consume. Further, these products are not typically flagged to be high-risk consumption foods to alert vulnerable populations such as infants, children, pregnant women, the elderly or immunocompromised persons that can be adversely affected by the causative agents of food borne illness or disease.

THE LACK OF ISSUANCE OF A FDA FORM 483 DOES NOT OBVIATE THAT INFRACTIONS AND OR VIOLATIONS OF THE FOOD DRUG AND COSMETIC ACT OCCURRED AND WERE OBSERVED BY THE FDA

It is well established and documented that the FDA inspector observed, noted and made five (5) observational findings in contravention of the FFDCA (FSMA) (See Exhibit 2).

Mr. Zicher touts the fact that a 483 was not issued, but does not exhibit the presence of mind to understand the severity of the findings or he intentionally minimizes the occurrences. Additionally, the FDA inspector pointed out that there seemed to be a systemic problem related to the record keeping, facility maintenance (dock doors)[17] and pest control due to the fact that the same issues identified at Bartlett in October of 2022 were also noted from her July 2022 inspection of the Elk Grove facility (See Exhibit 2 pg. 9).

Again, the lack of proper prerequisite and requisite programs underscore the observations made at both Elk Grove and Bartlett Creative Werks facilities, as well as the Nestlé audit findings.

MR. ZICHER'S CLAIMS OF BEING A DEGREED BIOCHEMIST AND/OR A B.S. IN SCIENCE

Mr. Zicher claims on his LinkedIn page to have a BS in science and at other times a BS in Biochemistry (See Exhibit 28 and Exhibit 29). This conduct of purporting to have a degree that he does not have or skills that he cannot evidence is egregious and unconscionable at best.

Further, this assertion of having a BS in Biochemistry is telling and is juxtaposed to the subpar quality of knowledge evidenced in his work product relative to even creating the HACCP plan

[17] Nestlé noted the deficiencies in the dock doors in their audit.

for the Dunkaroos non-compliant food safety plan. Mr. Zicher's overall approach to drafting the non-science-risk based document does not support his claim(s) of having a B.S. in Science let alone a B.S. in Biochemistry.

It is not likely and highly improbable that a degreed science major from an accredited institution in any applied science should lack fundamental concepts of scientific principles such as following established standardized methods. Nor should they lack basic understanding of the requests made by the FDA inspector in regards to record keeping or how to apply basic high-school science concepts to science risked based initiatives.

What is even more telling of Mr. Zicher's competency is that Mr. Zicher an alleged degreed Biochemist or some other degreed science major could not, did not and has not spoken to the issues raised relative to the non-conformities himself in any manner-lay, technical, scientific or otherwise.

Specifically, Mr. Zicher in no formidable way has ever rejected my contentions, provided any documentation, law, facts, peer review or by any other means or instrument been able to contradict or refute the actual issues that I raised. Further, he was unable to demonstrate how he reached the conclusions he asserted utilizing appropriate technical and scientific terms and principles to refute, reject or contradict the issues that I raised. This lack of responsiveness in a scientific professional manner is telling.

Additionally, Mr. Zicher never provided an action plan, inclusive of a plan of action, expectations, goals or any direction on how to approach remediating the outstanding customer and regulatory issues.

Mr. Zicher's same LinkedIn page does not support that he ever worked at Kraft as alleged. Mr. Zicher is not credible nor is he a qualified person by education, training and or job experience or a combination thereof as defined by the FDA (21 CFR 117.3) to function in the supervisory capacity of Director of Food Safety that he is operating in. (21 CFR 117.4(c))

Further, allowing someone to infiltrate the organization through a perpetration of "working at Kraft" or alleging to have a "BS in Biochemistry" is another indictment of Creative Werks inadequate food safety and defense programs and its inherent ability to comply with FSMA and the Bioterrorism Act of 2002 that require employers to vet their employees. 21 CFR 117.4 (a)

My intention was to steward closure to the compliance gaps at Creative Werks that had existed since the PCHF rule had been implemented in 2015, but was never complied with by Creative Werks[18]. Moreover, my hope was to create and build robust food safety and defense programs

[18] Creative Werks was non-compliant prior to Mr. Zicher becoming the Food Safety Director in 2020.

that attract and retain customers and to avoid negative goodwill and minimize any potential liability that may have resulted from the consumer complaint investigated by the FDA or any other complaint.

POST DOL Filing

I did not become aware that my suspension without pay (de facto termination) had transitioned to an official termination until Defendants had responded to the Department of Labour complaint in July of 2023.

Defendants for the first time asserted that I was incompetent and that was the basis for the alleged termination (See Exhibit 30).

I reject the contention or assertion that I am incompetent.

This is in contravention to the reasons asserted in the District Court for termination. The reason asserted for termination was after acquired evidence and/or policy violations. (DKt. #53 pg. 34 Affirmative Defense 2 & 3)

This reason also differs from the reason given to the IDHR for termination (See Exhibit 31).

Defendants, VP of HR, Gretchen LeMay, also told the IDHR that Plaintiff's suspension was moved to unpaid after I refused to respond to her calls (See Exhibit 31 pg---) Exhibit 20 is a group exhibit of emails from November 1, 2022 through November 8, 2022 specifically with Gretchen LeMay who transitioned me to a non paid suspension.

Specifically, Gretchen LeMay emailed me on November 1, 2022. I responded back to her email on November 2, 2022. LeMay responded on November 2, 2022. I also responded on November 2, 2022. LeMay responded on November 3, 2022. I responded on November 4, 2022 and against on November 7, 2022 twice and LeMay responded back on November 8, 2022, informing of the transition of my suspension from paid to non-paid (See Exhibit 20)

LeMay also told the IDHR that I never reported adverse employment actions to Defendants See Exhibit 31. This is in contradiction to Defendants' judicial admission that says otherwise. Dkt. #53, pg. 29, ¶95

LeMay also provided false and misleading information to the IDHR (See Exhibit 31) as to what my job responsibilities were in contravention to Defendants' admissions in their answers indicating that Plaintiff was responsible for regulatory and compliance. Dkt. #53, pg. 7, ¶8 LeMay also stated to the IDHR (See Exhibit 31) Plaintiff's report that was presented to the President included defamatory remarks regarding leadership.

To date, LeMay nor Defendants have been able to identify any defamatory remarks or errors of fact, law and science.

Defendants have knowingly been providing false, misleading and inconsistent information to various governmental agencies.

I have not been formally terminated by Defendants. I requested my personnel file twice; once in November of 2022 and again in January of 2023. Defendants admitted that there was not anything in my personnel file to support poor performance or termination and that no documents were withheld. Dkt. #53 pg. 28 ¶92

Defendants represented in open Court on the hearing of Plaintiff's Rule 11 motion that Defendants previous legal counsel of Ford Harrison represented to Plaintiff's legal counsel, Attorney Hoffman, in the Department of Labour matter that Plaintiff had been terminated.

I reject that contention as Mr. Hoffman at no juncture has represented to me that he has been notified that I had been terminated by Craig Thorstenson or any representative from the Law firm of Ford Harrison. See Exhibit 30 Declaration of Jordan T. Hoffman

Defendants were aware that Plaintiff did not have termination claims before the court and acknowledged and agreed to remove such language from the initial disclosure report that it was to prepare and file with the court. See Dkt. 41

Defendants attorney also told Plaintiff that she was not to police his litigation strategy (See Exhibit
32).

I did not discuss with Mr. Schroeder whether the Risk Analysis had been shared with Mr. Zicher. Rather, the conversation focused on the contents of the Risk Analysis itself and the underlying issues it raised. Plaintiff further noted that there had been prior correspondence with Mr. Zicher regarding the compliance concerns addressed in the Risk Analysis.

I, Mary Madison, declare under penalty of perjury that the foregoing is true and correct.

Dated: July 7, 2025 /s/ Mary Madison